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| 09/990,783  | 11/14/2001  | Yuch Ping Hsieh      | 90024               | 3137             |
| 9355  | 7590        | 07/22/2004           | EXAMINER            |                  |
| ALLEN, DYER, DOPPELT, MILBRATH & GILCHRIST, PA<br>P.O. BOX 3791<br>ORLANDO, FL 32802-3791 |             |                      | GAKH, YELENA G      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1743                |                  |

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/990,783

Applicant(s)

HSIEH ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13, drawn to a method for measuring an evolution rate, classified in class 436, subclass 56.
  - II. Claims 14-25, drawn to a device for measuring an evolution rate, classified in class 422, subclass 56.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the device can be used for conducting any reaction (claim 14) or conducting reactions involving a breath sample (claim 17).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Jacqueline E. Hartt on 05/21/04 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Specification*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The specification is objected to as not containing “a written description of the invention, ... in such full, clear, concise, and exact terms as to enable any person skilled in the art” to practice the invention in its best mode. In particular, it is not clear from the specification, which rate of a gas evolution in solids and liquids is determined by the method, if the micro-respirometer is constantly shaking at various speeds. It is well known from the prior art that agitating a vessel containing the sample, which produces carbon dioxide increases the rate of evolution by increasing the rates of forming the gas and diffusion from the sample into air (see e.g. Chicoye et al. US 4,068,005, col. 1, lines 43-53; “Shaking Soda Cans”). Therefore, shaking the microrespirometer changes the evolution rate of CO<sub>2</sub>, and thus the measurements do not reflect a “natural” evolution rate. There is no indication of this phenomenon in the specification. Rather, the specification refers only to increasing an absorption rate of carbon dioxide, obtained from non-analogous experiments of absorbing CO<sub>2</sub> by the reagent from the air. The latter is a different and much simpler physical-chemical process involving carbon dioxide, since it does not involve evolution of carbon dioxide from the liquid or solid sample and diffusion of the evolved gas into air. It is not clear, how the results of these experiments can be introduced into a more complex process of CO<sub>2</sub> evolution from the liquid or solid sample. The experiments are designed to optimize conventional parameters of CO<sub>2</sub> absorption, such as the shaking rate of the vessel, which increases diffusion of CO<sub>2</sub> into the reagent solution, and NaOH concentration. Experiment #4 is not clear. It just demonstrates increasing the rate of absorption with increasing CO<sub>2</sub> concentration, which is an obvious fact. It is not clear, what this experiment has to demonstrate, and how it can be used for the “real” case. As for the CO<sub>2</sub> absorption/evolution equilibrium, this part of the specification is not apparent to the examiner. According to the Merriam-Webster Online Dictionary, “an equilibrium is a state of balance between opposing forces or actions that is either static (as in a body acted on by forces whose resultant is zero) or dynamic (as in a reversible chemical reaction when the rates of reaction in both directions are

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equal)". It is not clear, which reversible reactions (or processes) are considered here. While evolution of  $\text{CO}_2$  can be considered a reversible process because of reversible  $\text{CO}_2$  diffusion between gaseous environment and the solid or liquid sample, absorption of  $\text{CO}_2$  by the disclosed system is irreversible, since  $\text{BaCO}_3$  is precipitated. It is not clear at all, how the equilibrium between two completely different processes can be reached, especially when one of the rates (of "natural" evolution) is not controllable, while the other is controlled by adjusting concentration of  $\text{NaOH}$ ? Theoretically it is possible to find the conditions, when the rate of absorption will be adjusted to be equal to the rate of evolution. However, the specification does not clearly disclose such adjustment. What is described in the "real" experiment (page 8) is reaching the first end point of titration with larger amount of  $\text{NaOH}$ , setting its time as a reference time, and adding another, a smaller aliquot of  $\text{NaOH}$  to measure the absorption rate of  $\text{CO}_2$  with a presumption that it is equal to the evolution rate of  $\text{CO}_2$ . It is not clear, what this experiment has to do with "equilibrating the sample with the alkaline solution". It is not apparent what the latter expression really means, since the sample is not even in a contact with the solution. Moreover, it is not clear, how Figure 4 should demonstrate that such equilibrium could be reached. It is not clear, where does the conclusions that "if the starting  $\text{CO}_2$  evolution rate of the sample 19 is  $100 \mu\text{L/h}$ , the  $\text{CO}_2$  concentration of the respirometer 11 is increased to about 660 ppm and remain there because an equilibrium of  $\text{CO}_2$  absorption and evolution is established" come from? Which experiment demonstrates this? Then, on page 10 the specification discloses evaluating a time period required for establishing this equilibrium through a mathematical relation between changes of  $\text{CO}_2$  concentration in the respirometer and difference in absorption and evolution rates. While it is clear, that what is called "equilibrium" is an equality of absorption and evolution rates, it is not clear, how this equality can be determined in practice. It is not clear, what is the process, which makes  $E$  equal  $A_{Ci}$  and the concentration  $C$  constant? Even less it is clear, how % of equilibration value can reach 400 (Figure 5), and what does Figure 5 demonstrates in general?

5. In "Brief Description of the Drawings" (page 4) the caption for Fig. 6 is not complete: it should read "a graph of  $\text{CO}_2$  evolution rate *measured by IR analyzer* versus the rate determined by the microrespirometer". It is also not apparent, which sample is used for this experiment.

In Figure 5 it is not clear, the equilibrated value of what is defined on y-axes.

*Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for measuring an evolution rate of carbon dioxide, does not reasonably provide enablement for measuring an evolution rate for any other gas. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claim 1 recites in its last step that “a carbon dioxide evolution rate” is calculated from the measurements conducted in the previous steps. The specification does not disclose any way of measuring an evolution rate of any other gas besides carbon dioxide from the calculated evolution rate of carbon dioxide.

The method is also enabled only for liquid or solid samples, since evolution occurs only for the gas present in the liquid or solid sample.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites in the preamble “measuring an evolution rate of a gas from a sample” and in the last step “calculating from the time increment a carbon dioxide evolution rate”. There is a contradiction between a description of the method given in the preamble and its actual essence. The claims should refer to “a method for measuring an evolution rate of carbon dioxide”.

It is not clear, what the expression “equilibrating a sample with a solution comprising an alkaline solution and a pH indicator” means, as there is no contact between the sample (liquid or solid) and the alkaline solution with pH indicator. If this “equilibrating” is what is disclosed in the specification as an equilibrium between evolution and absorption of CO<sub>2</sub>, the question

regarding description of such equilibrium is raised above. In any case, it is not clear, how “equilibrating” and “permitting the alkaline solution to absorb formed carbon dioxide in an enclosed space” can be separated in time? Since the recitation of the claims and disclosure in the specification are not clear and definite, the examiner interprets the step of “equilibrating” as the step of finding an end point of titration of CO<sub>2</sub> present in the headspace with NaOH.

From claims 2 and 3 it is not clear, which “evolution rate” is determined, since it is different from the evolution rate determined in the parent claim.

Claim 8 is completely unclear. What does it mean “the portion comprises substantially none of the solution”? That this portion does not exist?

In claim 13 it is not clear, which specific concentration is considered to correspond “M”, since the solution comprises two components: alkaline and pH indicator. “M” should refer to the alkaline concentration in the solution.

### *Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. **Claims 1-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (Abstract, 1999) in view of Harp (US 6,368,870 B1).

Baker teaches the equilibrium vapor method for determination of evolved CO<sub>2</sub>, which involves the measurement of CO<sub>2</sub> concentration in the headspace of a water sample by gas chromatography and calculation of total concentration of dissolved carbon dioxide by using equilibrium relations of the carbonate system, implying Henry's law. The method is most accurate when sample pH is low (near the alkalinity titration endpoint, about 4.3) when the standard titration method is least accurate or inapplicable. Equilibrium vapor method requires establishing equilibrium for all CO<sub>2</sub> in the system.

Baker does not specifically teach using NaOH-BaCl<sub>2</sub>-pH indicator system for detecting evolved CO<sub>2</sub>. Titration of evolved CO<sub>2</sub> with NaOH using pH indicator, especially phenolphthalein, to measure an amount and therefore the evolution rate of CO<sub>2</sub>, is a well-known technique (see e.g. references cited in Rowell, Soil Biol. Biochem., 1995). The method comprises the step of calculating the evolution rate based on the amount of the titrant absorbed in time.

It would have been obvious for anyone of ordinary skill in the art to modify equilibrium vapor method of Baker by using a simpler colorimetric technique recited in Rowell's references instead of gas chromatography, if pH of the sample is not very low (i.e. CO<sub>2</sub> concentration is not very high), since colorimetric technique is cheaper and well-suited to field studies (see Rowell, page 373, left column).

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Padawer* (US 3,865,548) discloses detecting CO<sub>2</sub> evolved from a biological sample by colorimetric method comprising entrapping CO<sub>2</sub> in alkaline solution with a pH indicator; *Fehder* (US 4,994,117) discloses a quantitative carbon dioxide detector, with a reagent



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comprising alkaline and pH indicator, with alkaline giving a reaction product, which is in equilibrium with CO<sub>2</sub>; *Harp (US 6,368,870 B1)* discloses controlled diffusion analysis for CO<sub>2</sub>; *Rowell (Soil Biol. Biochem., 1995)* teaches "colorimetric method for CO<sub>2</sub> measurement in soil" discussing equilibration with a dilute bicarbonate solution containing a pH indicator dye; *Grogan (Ecology, June 1998)* discloses "CO<sub>2</sub> flux measurement using soda lime: correction for water formed during CO<sub>2</sub> adsorption".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh  
7/20/04

